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APPLICATION NUMBER	08/736,267	FILING DATE	10/24/96	FIRST NAMED APPLICANT	BACKSTROM	ATTY. DOCKET NO.	K 06275/004001
						EXAMINER	

HM22/1230

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ART UNIT	PAPER NUMBER
LUKTON, D	35

1653

DATE MAILED: 12/30/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 11/23/99, 8/20/99

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 DAYS ~~months~~, or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

☒ Claim(s) 1-10, 12-16, 21, 22, 26-32, 50-97, 101 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☐ Claim(s) \_\_\_\_\_ is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☒ Claim(s) 1-10, 12-16, 21, 22, 26-32, 50-97, 101 are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

SEE OFFICE ACTION ON THE FOLLOWING PAGES--

The request filed on 8/20/99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/736267 is acceptable and a CPA has been established. An action on the CPA follows.

Pursuant to the directives of paper No. 30 (filed 7/6/99), claims 11, 98-100 have been cancelled, claim 101 added, and several claims amended. Claims 1-10, 12-16, 21, 22, 26-32, 50-97, 101 are pending.

\*

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 1, 3-10, 12-16, 101, drawn to a composition which does not contain a "non-hygroscopic additive", classified in, e.g., 514/002.
- II. Claims 1-10, 12-16, 62-77, 101, drawn to a composition which must contain a "non-hygroscopic additive", or alternatively must contain a carrier comprising particles having a diameter of at least 20 microns (as recited in claim 61) classified in, e.g., 514/002.
- III. Claims 21, 22, 26, 27, 28-32, 50-60 drawn to a method of systemic administration of a peptide-containing composition, classified in, e.g., 514/002.
- IV. Claims 78-97, drawn to an inhaler device, classified in, e.g., 424/46.

The claimed inventions are distinct.

Inventions I and II are related as combination and subcombination. Inventions in this

relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the subcombination can be used as such. In addition, Groups I and II differ on the basis of particle size.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). The two Groups are distinguished, in part, because the compositions could be used for nasal inhalation.

Inventions III and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process.

Notwithstanding the foregoing, in the event that Group I is elected and subsequently found allowable, the claims drawn to a method of administering the allowed compositions will be rejoined for allowance, or at least further examination [*In re Ochiai* (37 USPQ2d 1127)]. In addition, the claims drawn to the device will be rejoined. Further, in the event that Group I is elected and subsequently found allowable, it would be appropriate to revisit the

question of restriction between Groups I and II. It is more likely than not that rejoining would take place (subject of course to the same limitations). Thus, in the event that Group I is elected and found allowable it is entirely possible that the restriction will be withdrawn in its entirety.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Regardless of which Group is chosen, an election of a specific peptide (contained within the composition) is required. In the event that Group I is chosen, a second specie is a specific "surfactant compound". If Group II is chosen, each of the following species is required: (a) "surfactant compound", (b) an enhancer, and (c) a "hygroscopic additive". If Group III or IV is chosen, election of a specific "enhancer compound" is required.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance,

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if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'D. Lukton', is written over a circular stamp.

DAVID LUKTON  
PATENT EXAMINER  
GROUP 1000